

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: PHARMACEUTICAL INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION**

**MDL No. 1456**  
C.A. No. 01-12257-PBS

THIS DOCUMENT RELATES TO:  
ALL ACTIONS

Judge Patti B. Saris

**CERTAIN NAMED PLAINTIFFS' OPPOSITION TO CLASS PLAINTIFFS' MOTION  
TO ADD INDIVIDUAL PLAINTIFFS AS CLASS REPRESENTATIVES FOR TRACK  
TWO SETTLEMENT**

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## **I. Introduction**

Named Consumer Plaintiffs hereby oppose Class Plaintiffs' Motion to Add Individual Plaintiffs as Class Representatives for Track Two Settlement (Dkt. No. 7572).

At the outset, the Motion fails to set forth any standard. No legal precedent is cited, as if the novel task ahead were some well-trodden path. Indicative of the *laissez faire* legal environment in which Class Counsel have safely operated in recent years in this case, the Motion appears to assume it will be granted, cavalierly concluding its herculean and unprecedented request (to salvage the representation in a class action case involving a proposed \$125 million dollar settlement) in barely 5 terse pages of text.

The Motion, as presented, fails to demonstrate how any of the proposed individual consumers or association plaintiffs have standing to sue any of the Track 2 Defendants, as is required for this Court's exercise of jurisdiction under Article III of the United States Constitution. The Motion further fails to demonstrate how any of the proffered plaintiffs are typical or adequate representatives of any of the Track 2 proposed Consumer Class 1 Settlement Sub-Classes, especially in view of the late proffer of three (3) individuals more than ten (10) years after this case was first filed by PAL. For these reasons, the Motion should be denied.

## **II. Argument**

### **A. Legal Standards for Determining the Standing, Typicality and Adequacy of Representation of Proposed Representative Plaintiffs in Settlement Classes.**

While the Court at the Fairness Hearing seemed to be willing to pass on the question of standing of the proposed individual plaintiffs, there can be no doubt that Class Counsel bear the substantial burden of showing that the proffered individuals have both Article III and statutory

standing to sue,<sup>1</sup> and that they are typical (under Rule 23(a)(3)) and adequate (under Rule 23(a)(4)) to serve as representatives of the Class 1 consumer settlement Sub-Classes they seek to represent. *See, e.g., In re Average Wholesale Price Litig.*, 230 F.R.D. 61, 79 (D.Mass. 2005) (“[S]tanding ... frequently appear[s] as [a] threshold requirement[] for the maintenance of federal class actions and must be considered *in addition to* the requirements of Rule 23 when deciding whether a particular action may be certified.” (Emphasis added)(Citations omitted). Thus, satisfaction of this burden requires three separate showings by Class Counsel: (1) that each individual suffered some concrete injury-in-fact caused by one or more Track 2 Defendants, (2) that their claims against such Defendant(s) are typical of the claims of other putative Track 2 Class 1 consumer Sub-Class members, and (3) that they are adequate representatives of the Track 2 Class 1 consumer Sub-Classes, *i.e.*, knowledgeable, involved and zealous advocates of the rights of Class 1 consumers.

On **standing**, the Supreme Court has admonished:

It is axiomatic that the judicial power conferred by Art. III may not be exercised unless the plaintiff shows “that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant.” It is not enough that the conduct of which the plaintiff complains will injure *someone*. The complaining party must also show that he is within the class of persons who will be concretely affected. Nor does a plaintiff who has been subject to injurious conduct of one kind possess by virtue of that injury the necessary stake in litigating conduct of another kind, although similar, to which he has not been subject.

*Blum v. Yaretsky* 457 U.S. 991, 999 (1982) (citations omitted); *see also, Baker v. Carr*, 369 U.S. 186, 204 (1962)(plaintiffs need “such a personal stake in the outcome of the controversy as to assure ... concrete adverseness”). The First Circuit has echoed, “[i]f a party lacks standing, we have no jurisdiction to decide the merits of the case.” *Sea Shore Corp.*, 158 F.3d at 54 (citations omitted).

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<sup>1</sup> *Sea Shore Corp. v. Sullivan*, 158 F.3d 51, 54 (1<sup>st</sup> Cir. 1998)(“The burden of stating facts sufficient to support standing rests with the party seeking to assert federal jurisdiction.”)(citing *Warth v. Seldon*, 422 U.S. 490, 518 (1975)).

The issue of standing of the proposed individual and association plaintiffs presents the most difficult threshold question for this Court<sup>2</sup>: whether these plaintiffs can pursue claims, to the extent claims may be stated, based upon drugs they did not purchase, which drugs were manufactured by Track 2 Defendants they could not sue directly for damages. This issue is straightforward. It involves two layers of standing: **Article III standing and statutory standing**. First, the proposed plaintiffs must show Article III standing to sue each individual Track 2 Defendant<sup>3</sup>; *i.e.*, they “must demonstrate: (1) an ‘injury-in-fact’; (2) that is ‘fairly traceable’ to the proceeding below; and (3) ‘likely’ to be ‘redressed by a favorable decision.’”. *Sea Shore Corp.*, 158 F.2d at 55 (*citing Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Second, they must show that they have standing to assert class claims under the consumer fraud laws of their home states, including Georgia (Ms. Laday), West Virginia (Ms. Tonacchio), Pennsylvania (Mr. Trusky) and California (Ms. Swayze). *See, e.g., Payton v. County of Kane*, 308 F.3d 673, 680 (7<sup>th</sup> Cir. 2002)(noting that “statutory and Article III standing requirements must be addressed”).

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<sup>2</sup>

As Track 2 Defendant Pharmacia argued to this Court in opposition to class certification:

“Individual standing is a threshold issue for all actions, including class actions. As the Supreme Court has instructed, the fact “that a suit may be a class action ... adds nothing to the question of standing, for even named Plaintiffs who represent a class must allege *and show* that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.” Unless the proposed class representatives offer sufficient evidence to “demonstrate the requisite case or controversy between themselves personally and [defendants], none may seek relief on behalf of himself or any other member of the class.”

Defendant Pharmacia’s Individual Mem. in Opposition to Class Certification at Dkt. No. 2797 (“Pharmacia Mem.”) at 2 (emphasis in original)(citations omitted).

<sup>3</sup>

*In re AWP*, 230 F.R.D. at 79 (“[I]t is well settled that prior to the certification of a class, and technically speaking before any formal typicality or commonality review, the district court must determine that at least one named class representative has Article III standing to raise each class sub-claim.”)

On **typicality and adequacy of representation**, as Track 2 Defendants vehemently argued in opposition to class certification<sup>4</sup>:

[i]n order to fall within the class definition and to establish standing to pursue claims against [each individual Track 2 Defendant], each proposed representative must demonstrate that they (a) made some payment, (b) for a [Track 2 Defendant's] product at issue, © during the relevant time period, that was (d) based upon a published AWP for [the Track 2 Defendant's] product."

Pharmacia Mem. at 1.<sup>5</sup> These four (4) prongs must be met by Class Counsel to establish the standing of any putative class representative.

A class representative's claims are considered "typical" "when their injuries 'arise from the same events, practice or course of conduct of the defendants as do the injuries which form the basis of the class claims.'" *In re Eaton Vance Corp. Sec. Litig.*, 219 F.R.D. 38, 43 (D. Mass. 2003) (citation omitted). The typicality requirement ensures that when a proper class representative litigates its own claims, it will necessarily advance the interests of the entire class. *General Tele. Co. of Southwest v. Falcon*, 457 U.S. 147, 156 (1982).

Rule 23(a)(4) of the Federal Rules of Civil Procedure requires that the representative parties will "fairly and adequately assert and protect the interests of the class." Adequate representation assures due process of law to the unnamed class members. *Richard v. Jefferson County, Alabama*, 517 U.S. 793, 801 (1996); *Crawford v. Honig*, 37 F.3d 485, 487 (9th Cir.

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<sup>4</sup> Track 2 Defendants, who are the silent, co-movants along with Class Counsel in the Motion to Add Individual Plaintiffs for purposes of their jointly proposed Track 2 Settlement Class, should be judicially estopped from taking any legally inconsistent position at this juncture in the case. *See Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 32-33 (1st Cir.2004) ("As a general matter, the doctrine of judicial estoppel prevents a litigant from pressing a claim that is inconsistent with a position taken by that litigant either in a prior legal proceeding or in an earlier phase of the same legal proceeding.") (quoting *InterGen N.V. v. Grina*, 344 F.3d 134, 144 (1st Cir.2003)); *Cadle Co. v. Schlichtmann, Conway, Crowley & Hugo*, 338 F.3d 19, 22 (1<sup>st</sup> Cir. 2003)(same).

<sup>5</sup> *See also*, Dkt. Nos. 2789 (Abbott), 2830 (Aventis Pharmaceuticals), 2831 (Aventis Behring), 2801 (Amgen), 2800 (Immunex), 2794 (Baxter), 2687 (Bayer), 2836 (Dey), 2798 (Fujisawa), 2796 (Pfizer), 2797 (Pharmacia), 2826 (Sicor), and 2810 (Watson).

1994)(unnamed class members must have adequate representation if they are to be conclusively bound by the judgment in a class action).

As the Supreme Court in *Amchem* explained, to be considered adequate, “a class representative must be part of the class and ‘possess the same interest and suffer the same injury’ as the class members.” 521 U.S. at 625-26 (citations omitted). This provision requires that the named plaintiffs be willing and able to vigorously represent the interests of absent class members who will be bound by the outcome of the litigation. *Andrews v. Bechtel Power Corp.*, 780 F.2d 124, 130 (1<sup>st</sup> Cir. 1985). Adequate representation is a fiduciary obligation that demands the protection of class members’ interests through the class representative’s vigorous advocacy.<sup>6</sup> The fiduciary duty the class representative owes to class members requires that he or she engage in vigorous, informed settlement negotiations. *See, e.g., Butterworth v. Quick & Reilly, Inc.*, 171 F.R.D. 319, 323 (M.D. Fla. 1997) (collecting cases in which “courts have held that a plaintiff that does not understand the facts of the case, or her own claim cannot fulfill the role of the class representative”); *Coates v. Kelley*, 957 F.Supp. 1080, 1085 (E.D. Ark. 1997) (adequacy of named plaintiffs evidenced by “their vigorous negotiations on behalf of the national class”).

Adequacy is also a constitutional requirement. “[A]dequate representation is the foundation of all representative actions ....” *In re General Motors Corp. Engine Interchange Litig.*, 594 F.2d 1106, 1121 (7th Cir. 1979) (citing *Hansberry v. Lee*, 311 U.S. 32, 61 S.Ct 115, 85 L.Ed. 22

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<sup>6</sup> “[A] class representative, by assuming a representative role on behalf of the absent class members, [] accepts a fiduciary obligation toward the class that may not be abandoned at will or by agreement with the defendant if prejudice to the absent class members would inhere ....” *Blanchard v. EdgeMark Financial Corp.*, 175 F.R.D. 293, 298 (N.D. Ill. 1997). *See also, Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 549 (1949) (*emphasis added*). Indeed, the class representative must continue to satisfy those fiduciary obligations even after the resolution of the litigation. *Doe v. Heckler*, 580 F.Supp. 1224, 1229 (D. Md. 1984) (“[T]he fiduciary responsibility undertaken by the class representatives and their counsel to assure that the rights of unnamed class members are adequately represented ... does not end on the day a judgment is handed down”).



(1940)). *See also, Walker v. Liggett Group, Inc.*, 175 F.R.D. 226, 231 (S.D. W.Va. 1997)(“[t]he bedrock consideration for the court in any certification decision is ‘whether a proposed class has sufficient unity so that absent members can fairly be bound by decisions of class representatives’”).

As discussed below, a review of the records attached to the instant Motion to Add, as well as the sparse records pertaining to Ms. Swayze and Ms. Tonacchio that were produced in ostensible compliance with Magistrate Bowler’s June 9, 2011 Order, demonstrates that none of the newly-proffered putative representatives have standing to sue any of the Track 2 Defendants. But even assuming *arguendo* standing exists as to one or more individuals for one or more of the Track 2 defendants – which has not been shown and cannot be found on this record – Class Counsel otherwise have failed to demonstrate either typicality or adequacy of the proposed representatives pursuant to Rules 23(a)(3) and (a)(4), respectively.

**B. The Timing of Class Counsel’s Motion to Substitute Is Suspect and Calls Upon this Court to Order the Unprecedented Addition of Named Representative Plaintiffs After the Putative Class Claims Have Been Settled.**

At the Fairness Hearing, the Court raised, *sua sponte*, a “concern” about the timing of Class Counsel’s proposed Motion to Add Individual Plaintiffs. The Court was right to be concerned. As the Court remarked, and the undersigned has independently confirmed,<sup>7</sup> **there is no case** which stands for the proposition that the lawyers in a putative, uncertified class action may troll through the settlement claims administrator’s database of proposed settlement class claimants to find prospective plaintiffs to sponsor their lawyer-driven settlement. Furthermore, it would be

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<sup>7</sup> In response to the Court’s direct query, Mr. Berman also confirmed on the record that Class Counsel have been unable to find any case on point. The silence of the Defendants in the face of such inquiry speaks volumes about the lack of judicial precedent, given the substantial legal resources possessed by the myriad defense firms in this case. Moreover, as discussed below, many of the Defendants in this MDL have taken the view that putative class claims should be dismissed prior to class certification when there is no adequate class representative.

**bad policy** for federal courts to sanction a process that would encourage “lawyer’s lawsuits” to be filed, and to continue for years (even up to a decade), empowering the court-appointed “class counsel” to employ the *in terrorem* threat of a costly class action determination to bludgeon the defendants into settling. **Such a policy turns the requirements of *Amchem*** for “heightened attention” to and “rigorous analysis” of the class action prerequisites<sup>8</sup> in the settlement context – including, and especially, the requirement of adequate representation by fully “armed”<sup>9</sup> plaintiffs – **on their head.**

Prior to any class being certified for litigation purposes, as is the case in Track 2 here, if there are no plaintiffs with standing to sue, the case should be dismissed.<sup>10</sup> It has long been the law that “if none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of himself or any other member of the class.” *O’Shea v. Littleton*, 414 U.S. 488, 494 (1974). Indeed, the First Circuit explained that “courts have repeatedly held that the ‘predicate to [a plaintiff’s] right to represent the class is his eligibility to sue in his own right. What he may not achieve himself, he may not accomplish as a representative of a class’” *Diaz-Romos v. Hyundai Motor Co.*, 501 F.3d 12, 15 (1<sup>st</sup> cir. 2007)(quoting *Kauffman v. Dreyfus Fund, Inc.*, 434 F.2d 727, 734 (3d Cir. 1970)). As the late Professor Herbert B. Newberg further explains in his seminal treatise on class actions, “standing is

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<sup>8</sup> See *In re Polymedica Corp. Securities Litig.*, 432 F.3d 1, 6 (1<sup>st</sup> Cir. 2005)(“express(ing) [the First Circuit’s] preference for the majority view” of a “more demanding inquiry at the class-certification stage”, and reiterating that a “district court must conduct a rigorous analysis of the prerequisites established by Rule 23 before certifying a class.”)

<sup>9</sup> See *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 592 (1997)(noting that class counsel who “could not use the threat of litigation to press for a better offer” in settlement negotiations would be “disarmed”, and “the court would face a bargain proffered for its approval without benefit of adversarial investigation.”).

<sup>10</sup> See, Order dated March 29, 2011 at Dkt. No. 7483 (dismissing, without prejudice, the *certified* litigation “J&J subclass of Class 1” on finding that “plaintiffs have not demonstrated that Mrs. Oustad is an adequate class representative under Fed.R.Civ.P. 23(a)”).

the threshold issue in any suit. If the individual plaintiff lacks standing, the court need never reach the class action issue.” 3 Herbert B. Newberg on Class Actions § 3:19, at 400 (4th ed.2002); *see also, Lehman Brothers Securities and ERISA Litigation*, 2010 WL 545992, at \*3 (S.D.N.Y. Feb. 17, 2010) (pre-class-certification dismissal of securities claims for lack of standing proper where claims arose from securities offerings in which named plaintiffs did not participate).

**1. Standards for Substitution Pre-Class Certification Are Stringent, and Call for Dismissal of Class Claims After Reasonable Period of Time to Locate Substitute Plaintiffs.**

As the defendants in related AWP-litigation in New Jersey State court have argued:<sup>11</sup>

That this case is a putative class action does not change the rules for substituting a plaintiff in an action. As the First Circuit recently explained, “courts have repeatedly held that the ‘predicate to [a plaintiff’s] right to represent a class is his eligibility to sue in his own right. What he may not achieve himself, he may not accomplish as a representative of a class.’” *Diaz-Ramos v. Hyundai Motor Co.*, 501 F.3d 12, 15 (1st Cir. 2007) (quoting *Kauffman v. Dreyfus Fund, Inc.*, 434 F.2d 727, 734 (3d Cir. 1970)). “It is axiomatic that the procedural device” of a class action “cannot be allowed to expand the substance of the claims of class members.” *Broussard v. Meineke Disc. Muffler Shops, Inc.*, 155 F.3d 331, 345 (4<sup>th</sup> Cir. 1998). After all, the whole point of a class action is that it aggregates numerous individual “claims” into one action on the theory that that is more efficient than proceeding individually. *See IUOE (Merck)*, 192 N.J. at 384-94. Moreover, as the Third Circuit has stated, “[a] plaintiff who is unable to secure standing for himself is certainly not in a position to ‘fairly insure the adequate representation’ of those alleged to be similarly situated.” *Kauffman*, 434 F.2d at 734.

The defendants urge upon the State court the principle that, “prior to class certification, [the plaintiffs’] status as putative absent class members does not entitle them to become named plaintiffs or to prosecute the case without satisfying the same procedural hurdles required of all

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<sup>11</sup> See, e.g., Defendants’ Brief in Opposition to IUOE’s “Motion to Add Putative Class Representatives” (attached hereto as Exhibit “A”), one of many briefs on the subject filed by defendants in the case of *Int’l Union of Operating Engineers, Local 68 Welfare Fund, v. AstraZeneca, PLC, et al.* (“Defts’ IUOE Brief”), which case was remanded by this Court on April 14, 2006 (*see In re AWP*, 431 F Supp 2d 109 (D.Mass. 2006)).

new parties to any case.” *Id.* at 14 (citations omitted) In the absence of any legal precedent cited by either Class Counsel or Track 2 Defendants in support of their Motion to Add Individual Plaintiffs, these legal guideposts should, at a minimum, guide this Court’s decision. And, the failure to demonstrate, through any legal precedent or factual proffer, that the substitution of representative plaintiffs for Class 1 should be allowed pre-class certification, when the original association plaintiffs were found years ago to lack standing to sue for damages, should be the death knell to this lawyer’s lawsuit under consumer Track 2.

**2. Standards for Substitution Post-Class Certification Are Irrelevant, Since the Court Never Certified Any Track 2 Litigation Class.**

Class Counsel are likely to resort to citing cases in their Reply Brief that stand for the proposition that substitution of representative plaintiffs should be liberally allowed by courts. Such cases tend to deal with the issue of substitution after a litigation class has been certified. Accordingly, they are inapposite to the situation at bar: the substitution of representative plaintiffs to sponsor an already agreed-to settlement in a previously uncertified class case.

**3. Substitution Post-Settlement is Unprecedented, and Would Establish an Improper Policy Favoring “Lawyer’s Lawsuits” and “Disarmed Plaintiffs”.**

As the Court acknowledged at the June 13, 2011 Fairness Hearing, and the undersigned counsel has confirmed in independent research, there appears to be no case allowing the substitution of named class representatives in the context of a post-settlement class certification. Allowing substitution at this late stage of the proceedings would establish an unseemly policy favoring lawyer-driven lawsuits in which the named class representatives are relegated to “puppet” roles in which they simply endorse the decisions of class counsel, after the fact with little or no

input. Unnamed class members would be unfairly bound by such blind decisions made on their behalf.

The law is unambiguous that named plaintiffs are required to be more than window dressing or puppets for class counsel. *See, e.g., Kirkpatrick v. J.C. Bradford & Co.*, 827 F.2d 718, 727 (11<sup>th</sup> Cir. 1987); *Davidson v. Citizens Gas & Coke Util.*, 238 F.R.D. 225, 229 (S.D. Ind. 2006). Indeed, where the named plaintiffs have abandoned their role in the case beyond that of furnishing their names as plaintiffs, the attorneys, in fact, become the representatives of the class. *See Helfard v. Cenco*, 80 F.R.D. 1, 7-8 (N.D. Ill 1977). Courts have overwhelmingly ruled that an attorney may not serve both as class counsel and class representative. *See Susman v. Lincoln American Corp.*, 561 F.2d 86, 90-92 (7<sup>th</sup> Cir. 1977)(citations omitted)(collecting cases); *In re California Micro Devices Securities*, 168 F.R.D. 257, 260 (N.D. Calif. 1996). The danger of class counsel self-dealing is not limited to the situation in which the attorney serves as both class representative and class counsel; rather, it is present in every situation where class counsel is allowed to prosecute an action and to negotiate settlement terms without meaningful oversight by the class representative. *In re California Micro Devices Securities*, 168 F.R.D. at 262. Therefore, an informed and independent class representative is necessary to monitor class counsel at every stage of the litigation. *Id.* at 269-70.

It was Class Counsel's fiduciary obligation here to ensure that there was an adequate, informed and knowledgeable class representative involved at each stage of the Track 2 proceedings, especially settlement. *See Moore v. Halliburton Co.*, 2004 WL 2092019 (N.D.Tex. Sept. 9, 2004). Their failure to advise even the client they claim to have represented since 2007, Mrs. Swayze, constitutes the most serious breach of trust, infecting the result of their unmonitored

actions. The class attorney is supposed to be the guardian of the class with a fiduciary duty towards each member of the class. *In re Agent Orange Prod. Liab. Litig.*, 800 F.2d 14, 18 (2nd Cir. 1986). Class counsel must exercise due diligence and reasonable prudence in his conduct toward the class. *Class Plaintiffs v. City of Seattle*, 955 F.2d 1268, 1290 (9th Cir. 1992). The court may look at the performance of the proposed class counsel in class action litigation in judging adequacy. *Sullivan v. Chase Inv.*, 79 F.R.D. 246, 258 (N.D.Ca. 1978).

In seeking to substitute class representatives at this advance stage of the proceedings, pre-class certification but post settlement, Class Counsel show the lack of meaningful oversight by any class representative. As this court observed at the Fairness Hearing, the proposed class representatives were presented with a *fait accompli* for their endorsement. No court has ever endorsed such a class action policy.

**C. The Proffered Representative Plaintiffs Lack Standing to Sue, and Are Otherwise Not Typical or Adequate to Represent the Interests of the Track 2 Consumer Settlement Sub-Classes.**

**1. The Individual Absent Settlement Class Members Lack Standing, and Are Neither Typical or Adequate To Serve as Settlement Class Representatives at this Late Juncture**

In August 2005, in the context of ruling on Class Counsel's Motion for Class Certification for the Track 1 Defendants, this Court ordered Class Counsel that "when plaintiffs amend the complaint to propose individual class representatives [because the Court held that the same associations now proffered as class representatives did not have standing], they shall allege facts demonstrating typicality and adequacy of the class representatives and disclose the documents demonstrating that the proposed class representatives made co-insurance (at least in part) under Medicare Part B based on AWP." *In re AWP*, 230 F.R.D. at 81. Almost six (6) years later, Class

Counsel has failed to make such a showing with respect to any of the newly-proffered putative class representatives.

**a. Ms. Agnes Swayze**

Class Counsel's proffer as to Ms. Agnes Swayze fails to demonstrate how she has standing to sue any of the individual Track 2 Defendants, or that she *has served* as a typical or adequate Track 2 Class 1 consumer class representative since she became a class representative in June 2007. *See* Dkt. No. 7572 (attesting that she received injections of Anzamet, dexamethasone sodium phosphate, heparin sodium, Epogen and Neupogen, and that she paid all of her Medicare drug co-pays out-of-pocket.)

On **standing**, Class Counsel provided only select records – 7 to be exact – cherry-picked out of a volume of at least 104 records (as evidenced by the bates number of the last record produced). *See* ABS0104. (This is despite Magistrate Bowler's unambiguous Order that *all* billing and payment records were to have been produced.) These records show that Mrs. Swayze was administered five (5) drugs, only two (2) of which are single source, brand name drugs, Anzemet (Aventis) and Neupogen (Amgen). The other drugs, dexamethasone sodium phosphate, heparin sodium and Epogen are multi-source drugs. *See* Dkt. No. 3500.

For all the drugs, as discussed below, Mrs. Swayze's proffer fails to demonstrate that she made any payment based on the AWP of any Track 2 Defendants. Therefore, she fails prongs 1 and 4 of the above-stated test of standing. *See* Pharmacia Mem. at 1. For the multi-source drugs, heparin sodium and epoetin alpha, the proffer fails to identify the Track 2 Defendant manufacturer,

as required by prong 2. Dexamethasone sodium phosphate was stricken from the complaint by Court Order dated April 13, 2006. *See* Dkt. No. 3500.<sup>12</sup>

As for payment evidence, there is none. Class Counsel have attached to Mrs. Swayze's Affidavit (Dkt. No. 7572-1) certain limited billing, not payment records. However, these records list only J-Codes, and therefore do not provide any product identification for the multi-source drugs, heparin sodium and epoetin alpha. The records from her doctor's office, Valley Tumor Medical Group, although heavily redacted (the purpose for which redactions is not explained), clearly indicate that Mrs. Swayze did not make any payments for any of the drugs administered during the relevant time period. In fact, the columns at the top of each page of the billing records indicate that for each of the subject (unredacted) transactions the Patient Amount ("Pat. Amnt."), of the charge billed to Mrs. Swayze was zero. Relevant excerpts from the February 14, 2005 treatment with J1644 is recreated below for illustrative purposes:

<b>Charge</b>	<b>Pat. Amnt</b>	<b>Payment</b>	<b>Adjust</b>	<b>Balance</b>
10.00	0.00	-.10	-9.90	0.00

The third column from the left indicates a payment by her primary insurer ("Payment"), Medicare, with the next column representing an adjustment ("Adjust") and finally an end Balance of zero dollars. Similar adjustments were made for each and every transaction reflected in Mrs. Swayze's billing records from her doctor's office. These documents conclusively demonstrate that any outstanding balance after payment was made by Medicare was written off by the provider to reflect a zero balance. Mrs. Swayze had no further obligation to pay.

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<sup>12</sup> While Mrs. Swayze appears to have received other drugs in 2004 and 2005, these drug administrations are outside the time period, as required by prong 3 of the above standing test.



Similarly, the lone billing record from her treatment at Lancaster Community Hospital, page 7 of 13 of her Affidavit, which tracks payment by her primary insurer, Medicare, has a column for two (2) supplemental insurers, and indicates a Patient balance of zero dollars for each transaction. In fact, the record specifically states an “Account Balance” of “.00”, and a “Patient Balance” of “.00”. Once again, this document conclusively demonstrates Mrs. Swayze did not pay for any of her treatments, and no obligation to do so. Therefore, she has not standing.<sup>13</sup>

The settlement claim form attached to Mrs. Swayze’s Affidavit is of no moment. *See* discussion, *infra*, regarding Ms. Laday.

Lastly, when pressed by the undersigned, the 3 pages of documents were produced in response to Magistrate Bowler’s June 10, 2011 Order – ABS0104, ABS0080, and ABS0104. These were redacted in part. It is clear that Class Counsel redacted the word “Procrit” from Mrs. Swayze’s medical records. The original redacted documents, as produced to the undersigned before the Fairness Hearing, from which the naked-eye can easily read the word Procrit under Class Counsel’s black marker redaction, were filed of record with this Court during the Fairness Hearing as Certain Named Plaintiffs Exhibit “3”.

Such redaction is important in light of Class Counsel repeated representations to this Court that Ms. Swayze paid for the Amgen-manufactured version of Epoetin alfa, Epogen<sup>14</sup>. *See e.g.*, Dkt. No. 7572 at 3 of 7, Dkt. No. 7572-1 at ¶5. As late as the Fairness Hearing on June 13, 2011, Class Counsel presented a slide indicating that Ms. Swayze had taken Epogen. *See* Class

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<sup>13</sup> *See* Dkt. No. 7599 (wherein Class Counsel state “[w]e have examined all of Ms. Swayze’s medical records, the documents were [sic] have produced together with the ones we are producing today are the only documents that mention her being administered or paying for Track Two drugs.”)

<sup>14</sup> *See* discussion regarding epoetin alpha contained in the section addressing Mr. Trusky, *infra*.

Plaintiffs' Illustrative Slides in Support of Joint Motion for Final Approval of the Track Two Global Settlement Part 2, at p. 5. ("Fairness Hearing Slides"). In response to the Court's direct query regarding the proposed reallocation of the settlement proceeds to provide zero dollars to Epogen Class members, Mr. Berman stated that he would consult with those clients and explain the reallocation to them. Mrs. Swayze is not such a client, as has been falsely represented.

In light of Magistrate Bowler's Order calling for complete production of billing and payment records, Class Counsel's violation of their duty of candor to the tribunal, indeed promulgation of a deliberate falsehood in court, is unconscionable given the importance of Epogen. Prior to this filing, the undersigned asked Class Counsel to produce the original, unredacted copies of ABS0080 and ABS0082. *See* Letter dated June 14, 2011, attached as Exhibit "B". Class Counsel refused. *See id.* The Court should examine *in camera* the original redacted document at Named Plaintiffs Exhibit No. 3 to see the deliberate effort to deceive the Court and to conceal their false representations about Mrs. Swayze's purchase of Epogen.

On **typicality and adequacy**, Class Counsel point out that Ms. Swayze "has been an active participant in the AWP litigations since June 2007." Motion at 3. Although this case settled in March 2008, Ms. Swayze was not proffered as a representative for the Track 2 consumer subclass until June 1, 2011. Indeed, she has never been proffered for the J&J Class, when she clearly took Procrit. Class Counsel have not explained why Ms. Swayze was not involved in the settlement negotiations for the instant settlement. While Ms. Swayze was chosen to represent the BMS settlement class in 2007, she nonetheless failed to enhance the consumer payout in the face of a demonstrably deficient settlement. It took Rev. Aaronson to remedy the situation. On this

record, this Court cannot find that Agnes Swayze is an adequate representative of the Track 2 consumer interests.

**b. Ms. Mariella Laday**

Class Counsel's proffer as to Ms. Mariella Laday fails to demonstrate how she has standing to sue any of the individual Track 2 Defendants, or how she is a typical or adequate class representative. *See* Dkt. No. 7572 (attesting that she received various Track 2 Drugs and that she paid all of her Medicare drug co-pays out-of-pocket.). Specifically, Class Counsel have proffered Ms. Laday based on her treatment with Accuneb, Adenosine, Aristopan, Gamimune N, Gammagard, Ketorolac, Lyphocin, methotrexate sodium, and sodium chloride. *See* Fairness Hearing Slides at 5.

On **standing**, Class Counsel have not provided a single billing or payment record, though ordered to do so. Further, only 2 of the 9 drugs listed for Ms. Laday are single source, brand name drugs, Accuneb (Dey) and Ketorolac (Baxter), and neither of those drugs should be part of this settlement. *See* Dkt. No. 3500 at page 6 of 10 (listing the Dey drugs) and page 5 of 10 (listing the Baxter drugs). The other drugs, Adenosine, Aristopan, Gamimune N, Gammagard, Lyphocin, methotrexate sodium, and sodium chloride are multi-source drugs for which no manufacturer is identified. *See* Dkt. No. 3500.

Ms. Laday's proffer fails to demonstrate that she made any payment based on the AWP of any Track 2 Defendants. (The settlement claim form is not evidence.<sup>15</sup>) Therefore, she fails prongs 1 and 4 of the above-stated test of standing. *See* Pharmacia Mem. at 1. Further, because

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<sup>15</sup> In fact, Class Counsel recognized that most beneficiaries identified by such CMS data "are not Class Members because they had full supplemental insurance coverage." *See* Dkt. No. 5446 at 10 of 30; *see also* FN5, *supra*, citing estoppel jurisprudence.

Accuneb and Ketorolac are not part of the settlement, the only drugs at issue for Ms. Laday are the multi-source drugs, for which the proffer fails to identify the Track 2 Defendant manufacturer, as required by prong 2.

On statutory standing, this Court already has ruled that Ms. Laday, who was administered certain drugs as a patient at Piedmont Hospital in Atlanta, Georgia, Dkt. 7572-2 at ¶3, has no right to pursue any class claims under the Georgia Consumer Protection Statute, because that statute does not permit class actions. *See In re AWP*, 233 F.R.D. 229, 230 (D.Mass.,2006).

**c. Mr. Thomas Trusky**

Class Counsel's proffer as to Mr. Thomas Trusky fails to demonstrate how he has standing to sue, on behalf of the estate of his wife, any of the individual Track 2 Defendants, or that he is a typical and adequate class representative. *See* Dkt. No. 7572 (attesting that she received various Track 2 Drugs and that she paid all of her Medicare drug co-pays out-of-pocket up to the \$4,000 deductible.). Specifically, Class Counsel have proffered Mr. Trusky as an adequate representative based on his wife's treatment with Neulasta, Neupogen, Adenosine, Doxorubicin, sodium chloride, Dexamethasone, Cisplatin, Mannitol, alcohol injection, and Epogen. *See* Fairness Hearing Slides at 5.

On **standing**, as discussed below, Class Counsel provided only select records - 2 to be exact - with corresponding credit card receipts. Only 2 of the 10 drugs listed for Mr. Trusky are single source, brand name drugs, Neulasta (Amgen) and Neupogen (Amgen). *See* Dkt. No. 3500 at page 4 of 10 (listing the Amgen drugs) and page 5 of 10 (listing the Baxter drugs). Further, Cisplatin is not at issue in Track 2. *Id.* at 5 of 10. The other drugs are multi-source drugs. *See* Dkt. No. 3500.

With the exception of Amgen's Neulasta, Mr. Trusky's proffer fails to demonstrate that his wife made any payment based on the AWP of Track 2 Drugs during the relevant time period. Therefore, he fails prongs 1 and 4 of the above-stated test of standing. *See* Pharmacia Mem. at 1. With respect to Neulasta, Mr. Trusky's proffer, although demonstrating some payment for the drug in 2004, fails to demonstrate prong 3, a payment during the relevant time period. (The reference in 2003 states, "Paid by Empire"). *See In re AWP*, 460 F.Supp.2d 277, 288 (D.Mass. 2006) (limiting the class period to 1991 through December 31, 2003); *See also*, Order dated March 29, 2011, at Dkt. No. 7483 (holding that Mrs. Jimmie Ousted is not an adequate class representative because Class Counsel were "unable to locate written records demonstrating that Mrs. Oustad took Remicade prior to May 2004.").

Lastly, because the remaining drugs are multi-source drugs, Mr. Trusky fails to identify the Track 2 Defendant manufacturer, as required by prong 2.<sup>16</sup>

For example, epoetin alfa is the generic name for both Epogen (Amgen) and Procrit (J&J). As Amgen pointed out to this Court in its Opposition to class certification (Dkt. No. 2801):

Epogen and Ortho Biotech's Procrit are the same biologic (Epoetin alfa), but are marketed for different indications. The codes assigned to Epoetin alfa distinguish different uses but do not distinguish between the two brands. Thus, an individualized inquiry is required of every payment for Epoetin alfa to determine if the payment was for Epogen or for Procrit. Neither drug is commonly referred to in provider statements by brand name, but instead, is typically referred to simply as Epoetin alfa or by one of the J codes.

*Id.* at 1.

It is impossible on this record to determine whether Mrs. Trusky received epoetin alfa from Amgen or J&J. Further, given the record of Class Counsel's deceit on this particular issue, any

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<sup>16</sup> As discussed above, Mr. Trusky has met prong 1 and 2 of the standing test with respect to epoetin alpha and doxorubicin, however he has not shown that the drugs were manufactured by any Track 2 Defendant. He has not met any of the standing prongs for the other multi-source drugs.

proffered Affidavits are suspect. Such deceit also raises concerns about what the individual plaintiffs knew, affecting their adequacy to serve as class representatives.

**(4) Muriel Tonacchio**

Class Counsel has not adequately addressed the prior briefing on the lack of standing, atypicality and inadequacy of Ms. Tonacchio, *see* Dkt. No. 5971, which is incorporated herein. Rather, they continue to rely on a two page excerpt of Ms. Mort's medical records and the affidavit of her daughter, Ms. Tonacchio. Ms. Tonacchio's proffer fails to establish that her mother actually paid for her treatment with Anzemet. Ms. Tonacchio only gives her lay opinion that "it is [her] understanding" the excerpted records attached to her Affidavit "reflect" Ms. Mort's payment. Dkt. No. 5409-2 at ¶3<sup>17</sup> A similar approach was made by Class Counsel with respect to the claims against J&J. *Compare* Dkt. No. 7130 at ¶3 *with* Dkt. No. 7259. This Court agreed with J&J and reversed its preliminary approval of Ms. Ousted as an adequate representative, dismissing the class claims without prejudice. Dkt. No. 7483.

**2. The Association Plaintiffs Lack Standing to Represent Any Settlement Class for Either Damages or an Injunction, and Were Neither Typical nor Adequate to Serve as Settlement Class Representatives at Any Point in this Case.**

As detailed in Named Consumer Plaintiffs Omnibus Objection,<sup>18</sup> the Association Plaintiffs lack standing to sue, and are atypical and inadequate Track 2 Settlement Class representatives.

At least twice since this Court ruled in August 2005 that the Association Plaintiffs here lack standing to sue, the First Circuit has held that where, as here, an association has not alleged or

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<sup>17</sup> She also presents dismissable hearsay evidence regarding what an employee of Weirton Medical Center told her.

<sup>18</sup> *See* Omnibus Objection of Named Consumer Plaintiffs in Opposition to Approval of the Proposed Track Two Nationwide Class Certification and Settlement at Dkt. No. 7556.

demonstrated that any of its members possess standing to sue in his or her own right that association lacks standing.<sup>19</sup> Here, the Associations do not allege that any member paid for any Track 2 drug.

While this Court previously certified HCFA as a Track 1 class representative for a Rule 23(b)(2) litigation class, HCFA has withdrawn and no injunction was achieved in settlement. Therefore, the failure of any association plaintiff to achieve that which it was deemed adequate to obtain on behalf of the class in this case, shows lack of adequate representation for consumers.<sup>20</sup>

### III. Conclusion

For the foregoing reasons, the Motion to Add Individual Plaintiffs should be denied.

Dated: June 14, 2011

Respectfully submitted,

/s/ Donald E. Haviland, Jr.  
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<sup>19</sup> See *United Seniors Ass'n, Inc. v. Philip Morris USA*, 500 F.3d 19, 23 (1<sup>st</sup> Cir. 2007); *Me. Peoples Alliance & Natural Res. Def. Counsel v. Mallinckrodt, Inc.*, 471 F.3d 277 (1<sup>st</sup> Cir. 2006).

<sup>20</sup> Courts have long characterized the class representative as standing as a fiduciary to the class. See *Kline v. Wolf*, 702 F.2d 400, 402 (2d Cir.1983) (citing *Cohen v. Beneficial Industrial Loan Corp.*, 337 U.S. 541, 549-50 (1949) (“class representative is a fiduciary, and interests of the class are ‘dependent upon his diligence, wisdom and integrity’ ”); *Lane v. Page* 272 F.R.D. 558, 577 -578 (D.N.M. 2011)(citing *Robinson v. Gillespie*, 219 F.R.D. 179, 186 (D.Kan.2003) (“Having a fiduciary obligation to the putative class, class representatives must have the character and means to carry out that obligation....”); *Kelley v. Mid-Am. Racing Stables, Inc.*, 139 F.R.D. 405, 409 (W.D.Okla.1990) (“[N]amed plaintiffs might not qualify as adequate representatives because they do not possess the personal characteristics and integrity necessary to fulfill the fiduciary role of class representative.”).

**CERTIFICATE OF SERVICE**

I, Donald E. Haviland, Jr., hereby certify that on June 14, 2011 a true and correct copy of the foregoing Certain Named Plaintiffs' Opposition to Class Plaintiffs' Motion to Add Individual Plaintiffs as Class Representatives for Track Two Settlement was served on all counsel of record via CM/ECF notification.

/s/ Donald E. Haviland, Jr.

Donald E. Haviland, Jr.